DYNA-HEX 2- chlorhexidine gluconate 2% solution Xttrium Laboratories, Inc.

2% Dyna-Hex, 18-oz

Drug Facts

Active ingredient

chlorhexidine gluconate 2% solution

Purpose

antiseptic

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter
 and remain in the eye or may cause deafness when instilled in the middle ear through perforated
 eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Stop use and ask a doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:

- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with 8 mL of product (6 full pumps) with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product (6 full pumps) and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense 5 mL of product (4 full pumps) into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Skin wound and general skin cleansing:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other information

- store at 20-25° C (68-77° F)
- avoid excessive heat above 40° C (104° F)

Inactive ingredients

citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?

call **1-800-587-3721** Monday through Friday 8:00 AM to 4:30 PM CST

NDC 0116-1022-18

DYNA-HEX 2®

Chlorhexidine Gluconate 2% Solution

Antiseptic

Contains: 2% Chlorhexidine Gluconate With Foaming Pump

Distributed By: Xttrium Laboratories, Inc. Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 18 fl oz (532 mL)

2DYN18BTLLBLA



Drug Facts (continued)

Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

When using this product

- keep out of ears, eyes and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin-cleansing of large body-areas -should not be done except when advised by a health care provider

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:

- wet hands and forearms under running water for 30 seconds. Clean fingernalls using a nailstick or similar cleaner.
- scrub for 1.5 minutes with 8 mL of product (6 full pumps) with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product (6 full pumps) and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash: wet hands with water

- dispense 5 mL of product (4 full pumps) into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Drug Facts (continued)

Skin wound and general skin cleansing:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?

call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:

Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

DYNA-HEX 2

chlorhexidine gluconate 2% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-1022

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength CHLORHEXIDINE GLUCONATE (UNII: MOR8 4MUD8 E) (CHLORHEXIDINE UNII:R4KO0 DY52L) CHLORHEXIDINE GLUCONATE in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)		
WATER (UNII: 059QF0KO0R)		

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:0116-1022-18	535 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/29/20 16	

	Marketing Infor	mation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NDA	NDA019422	01/29/2016	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xttrium Laboratories, Inc.		007470579	manufacture(0116-1022)	

Revised: 10/2020 Xttrium Laboratories, Inc.